DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 4, 2014

PHILOSYS, INC.
C/O LINDA CHAN
PHILOSYS, INC
304 PARK AVENUE SOUTH, SUITE 218
NEW YORK NY 10010

Re: K131230
Trade/Device Name: Gmate® SMART Blood Glucose Monitoring System,
Gmate® SMART Application
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, CGA, JQP
Dated: July 28, 2014
Received: July 29, 2014

Dear Ms. Linda Chan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K131230

Device Name
Gmate® SMART Blood Glucose Monitoring System

Indications for Use *(Describe)*

The Gmate® SMART Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, thigh or calf. The Gmate® SMART Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The Gmate® SMART Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home to monitor the effectiveness of diabetes control. The Gmate® SMART should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternate site testing should be done only during steady state times (when glucose is not changing rapidly).

The Gmate® Blood Glucose Test Strips are for use with the GMATE® SMART Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, thigh or calf.

The Gmate™ SMART App is a component of the Gmate® SMART Blood Glucose Monitoring System and is intended to be used by people with diabetes at home as an aid to monitor and track the effectiveness of their diabetes management. The Gmate™ SMART App allows the user to view their glucose test results and store a lifetime of results. The user may e-mail their glucose test results to their healthcare provider to help them review, analyze, and evaluate their glucose test results to support an effective diabetes management program. The user can also graph and trend their glucose test results to provide an outlook of their diabetes management.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Stayce Beck -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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510(k) SUMMARY

(As required by 21.CFR.807.92)

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Submitted By:

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Contact Person:

Linda Chan
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Email: lchan@usdiagnostics.net

Date Summary, Prepared:

April 29, 2013

Device Name:

Propriety Name:
Gmate® SMART Blood Glucose Monitoring System
Gmate® SMART Application

Model Number: PG-101

Common Name: Blood Glucose Test System, Blood Glucose Monitoring System

Classification Name: Blood Glucose, Test, System, Glucose Oxidase, over the counter

Product Code	Classification	Regulation Section	Panel
CGA	II	21 CFR 862.1345	Chemistry (75)
NBW	II	21 CFR 862.1345	Chemistry (75)
JQP	I	21 CFR 862.2100	Chemistry (75)

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Predicate Device:

We claim substantial equivalence to:
1) K103544 – AgaMatrix, Inc. iBGStar System.

Device Description:

The Gmate® SMART Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood. The Gmate® SMART System is intended for self-testing outside the body (in vitro diagnostic use only) by people with diabetes at home as an aid to monitor the effectiveness of their diabetes management.

The Gmate® SMART Blood Glucose Monitoring System consists of a glucose meter, test strips, and one control material (additional levels of control material are available upon request). The small Gmate® SMART meter does not require coding or calibration, no need of batteries, and no settings are required. The Gmate® SMART meter is powered on by plugging it into the headphone jack of the Apple device. Insert the test strip into the meter, apply the blood or control solution to the strip and the meter will begin the 5 seconds count down of your test result. The Gmate™ SMART App converts the signal generated from the meter and test strip and displays the test result on the Apple device.

The Gmate® SMART Blood Glucose Monitoring System uses the smartphone technology, currently Apple's iOS (with use of the Apple iPhone 3GS, iPhone 4, iPhone 4S, iPhone 5, iPod Touch 4th generation, iPad, and iPad2), to view glucose test results. A simple download of the Gmate® SMART App, enables use of many functions.

The Gmate™ SMART App is a component of the Gmate® SMART Blood Glucose Monitoring System and is intended to be used by people with diabetes at home as an aid to monitor and track the effectiveness of their diabetes management. The Gmate™ SMART App allows the user to view their glucose test results and store a lifetime of results. The user may e-mail their glucose test results to their healthcare provider or healthcare provider to help them review, analyze, and evaluate their glucose test results to support an effective diabetes management program. The user can also graph and trend their glucose test results to provide an outlook of their diabetes management.

The test principle is:
This device is an in vitro diagnostic only product intended for the measurement of glucose concentration in human blood. The principle of the test relies upon a specific type of glucose in the blood sample, the glucose oxidase that reacts to electrodes in the test strip. The test strip employs an electrochemical signal generating an electrical current that will stimulate a chemical reaction. The meter measures the current and calculates your blood glucose level. Combined with the Gmate™ SMART App, it displays the test result and stores them on your Apple device.

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Intended Use:

The Gmate® SMART Blood Glucose Monitoring System is intended for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm, upper arm, palm, thigh or calf. The Gmate® SMART Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

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Comparison to Predicate Device:

The indication for use and the scientific technology of the Gmate® SMART Blood Glucose Monitoring System and the predicate device are similar. There are few items of the specifications such as test range, storage conditions are different. The performance testing data demonstrated that those differences do not raise issues of safety and effectiveness. Therefore, based on the information provided in this Premarket notification, we conclude that the Gmate® SMART Blood Glucose Monitoring System is safe, effective, and substantially equivalent to the predicate device as described herein.

Performance Data:

Non-clinical and clinical tests for the Gmate® SMART Blood Glucose System were performed in accordance with ISO15197 and other reference standards. The clinical performance evaluation testing included system accuracy, user performance, and alternative-site blood glucose measurement. The non-clinical performance evaluations were conducted to establish the performance, the functionality and the reliability characteristics of the Gmate® SMART Blood Glucose System. The devices passed all of the tests based on pre-determined Pass/Fail Criteria.

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Conclusion: The Gmate SMART Blood Glucose Monitoring System is safe and effective and substantially equivalent to K103544 – AgaMatrix, Inc. IBGStar System.